ASX RELEASE

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PARADIGM ENTERS INTO HEADS OF AGREEMENT WITH THE US BASED PRO PLAYERS ELITE NETWORK

Key Highlights:

- Paradigm is pleased to announce it has entered into a Heads of Agreement regarding a strategic partnership with the US based Pro Players' Elite Network to assist with recruiting and commencing treatment of US based sportspeople, via their doctors, under a proposed FDA Expanded Access program commonly referred to as the 'Compassionate Use' program.
- The Pro Players' Elite Network is a membership organization of over eleven thousand retired NFL players and elite athletes.
- The Pro Players Elite Network also has a charitable component to their network that is committed to creating awareness about the National opioid epidemic and the impact opioid pain medications have on professional athletes who suffer from the long-term effects of sport induced pain.
- Paradigm intends on replicating the success it has had in Australia, via the Therapeutic Goods Administration's Special Access Scheme (TGA SAS), in the US by treating various US elite sportspeople under the FDA's Expanded Use Program.
- The data gathered from treating US patients will add to the growing body of Real World Evidence (RWE) collected from Australian patients and will assist with the US FDA regulatory process.
- By initiating treatment of US based elite sportspeople, Paradigm expects to dramatically raise its profile globally.

Paradigm Biopharmaceuticals Ltd (ASX: PAR) is pleased to announce it has entered into a Heads of Agreement (HoA) regarding a strategic partnership with the New York, USA, based retired professional sporting network organization, the Pro Players' Elite Network (PPEN). The PPEN is a membership organization of over eleven thousand retired NFL players & elite athletes.

The HoA between Paradigm and the Pro Players Elite Network aims to identify and assist elite US sportspeople that have existing knee and joint pathologies that would benefit from treatment with injectable Pentosan Polysulfate Sodium (iPPS).

Paradigm views this partnership as a logical step forward, providing an excellent opportunity to not only treat people in need, but to gain significant exposure and promotion of the Company and iPPS in the US. The US market is a key focus for Paradigm, given the significant number of OA sufferers (31 million) and in particular the large number of sportspeople and NFL players suffering from OA who are being prescribed opioids to treat chronic pain[1].

[11] https://source.wustl.edu/2011/01/retired-nfl-players-misuse-painkillers-more-than-general-population/

The PPEN has an extremely large network and trusted relationships amongst the ex-NFL Player community and has experience in driving high levels of participation on similar projects. Recently the PPEN successfully recruited, in a matter of months, over 150 retired players for a study involving the use of Cannabidiol (CBD) for chronic pain.

PPEN has strong relationships with the NFL Retired Players Association (NFRPA), the NFL Alumni Association Chapters across the US (NFLAA), Athletes For Care, After the Impact (Non-Profit Organization who combats opiate addiction with numerous top NFL 'Hall of Famers' and US Generals sitting on its various committees and boards.

The PPEN also has a Charitable component to its network that is committed to creating awareness about the opioid epidemic and the impact opioid pain medications have on professional athletes who suffer from the long-term effects of sport induced pain.

Paradigm is confident that the TGA SAS results (average of 51.5% or greater pain reduction for knee OA pain), produced from 125 patients treated by their doctors in Australia, will be able to be replicated in the US. This would then provide valuable RWE data that supplements and diversifies the data already produced in Australia.

Both Paradigm and the PPEN share the same desire in treating patients in the US given the scope of the opioid epidemic and the lack of safe, effective non-opioid pain treatments. In addition, both parties are acutely aware of the proportionately high number of retired sportspeople[2], in particular NFL players[3], that have chronic joint pain and no effective treatment for that pain.

Importantly, the PPEN network membership, and specifically CEO Mitch Marrow's inter-network relationships in the local New York area consists of some very high profile ex-players and is one of the stronger PPEN regions nationally, which will bode well for working with prominent sports clinics and hospitals based in the New York area.

The PPEN will be responsible for identifying and assisting with the recruitment of patients as well as assisting with any associated media surrounding high profile US sportspeople that are treated with iPPS.

The PPEN also leverages strategic partnerships with leading educational providers, recovery centers and the medical community and is committed to helping its various members and the Public to understand the effects of opioids and identify less harmful alternatives.

Mr. Paul Rennie, Paradigm's Chief Executive Officer said: *"We are very pleased to announce this Heads of Agreement with the Pro Players Elite Network based in New York.*

"Given the success we have had treating both current and retired sportspeople in Australia, Paradigm has been actively exploring ways to enter the US and provide greatly needed treatments to US past elite sportspeople. Working with past elite sporting organizations, such as the Pro Players Elite Network, allows us to gain access to a range of sportspeople in the US who would be ideal treatment candidates for iPPS and this in turn will provide valuable Real-World Evidence for Paradigm. In addition, Paradigm will be able to work with and leverage the various sporting medical relationships that the Pro Players Elite Network has in US, which can potentially expedite our future US programs.

[2] https://www.reuters.com/article/us-elite-athletes-arthritis/elite-athletes-at-greater-risk-for-arthritis-idUSTRE7BF24920111216
[3] Page 27, http://ns.umich.edu/Releases/2009/Sep09/FinalReport.pdf

"Furthermore, there is significant common ground between what Paradigm is trying to achieve by being the world's first non-opioid, non-steroidal, non-addictive effective long-term treatment for chronic joint pain and the Pro Players' Elite Network's desire to help combat the opioid problem amongst retired sportspeople and the community at large."

Mr. Mitch Marrow, CEO of the Pro Players Elite Network said: *"The opportunity to work with Paradigm is something that we are truly excited about. The PPEN will be able to utilize its established contacts and relationships with various NFL retired players and other elite sportspeople organizations, including the NFL Retired Players Association.*

"It is well documented that ex-elite sportspeople, especially football players, have higher rates of joint injuries than members of the general population and therefore are at a higher risk of developing chronic joint pain.

"The PPEN are concerned about the use of opioids to manage chronic joint pain and are passionate about helping find new treatments for pain that are non-opioid and non-addictive and lead to better past-player welfare.

"The PPEN understands the success that Australian Doctors have had, via the TGA Special Access Scheme, in treating Australian Rules Football players as well people from the general public and we are looking forward to partnering with Paradigm Biopharmaceuticals."

About Expanded Access Program

Expanded access (sometimes called "compassionate use") is the use of investigational drugs, biologics or medical devices outside the clinical trial setting for treatment purposes. Expanded access may be appropriate when all the following apply:

- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrolment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.
- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.

Any person, in the USA, treated with iPPS by their Doctor will be done so adhering to all the USA FDA compassionate use regulations.

Given the debilitating nature of osteoarthritis, the lack of effective treatments and the compounding pressures of the opioid epidemic which is now responsible for 115 overdose deaths per day in the US, Paradigm and its regulatory advisors are confident iPPS non-opioid pain relief will be strongly considered for Expanded Access in the USA.

About injectable PPS

Injectable PPS is not currently registered in the US or Australia, but it is registered in four of the seven major global pharmaceutical markets. In those European markets, injectable PPS is registered as an

antithrombotic agent. In Australia, injectable PPS for human use is not currently available for sale. Injectable PPS for human use is only available by inclusion into a Paradigm Sponsored clinical trial or via a treating physician applying for its use in patients via the TGA's SAS - Category B. In the US, Paradigm intends on treating suitable patients that are referred by their treating physician via the FDA's Expanded Access program, commonly called the Compassionate Use program.

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